



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

MAR , 1 1993

Re: AMBIEN®  
Docket No. 93E-0087

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Charles E. Van Horn  
Patent Policy and Projects Administrator  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,382,938 filed by Synthelabo under 35 U.S.C. § 156. The human drug product claimed by the patent is AMBIEN® (zolpidem tartrate), which was assigned New Drug Application (NDA) No. 19-908.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product.

The NDA was approved on December 16, 1992, which makes the submission of the patent term extension application on January 25, 1993, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Douglas P. Mueller  
Wegner, Cantor, Mueller & Player  
P.O. Box 18218  
Washington, DC 20036-8218